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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,802	07/22/2003	Martin C. M. M. Barnardo	1181-282	5302

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EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
09/04/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary	Application No.	Applicant(s)	
	10/623,802	BARNARDO ET AL.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-25,34-37,46 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-25,34-37,46 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/04/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/04/08 has been entered. Currently, claims 22-25, 34-37, 46 and 47 are pending and under examination.

Rejections Withdrawn

In light of Applicant's remarks filed 08/04/08 on pages 3-4, the 112 2nd rejections of MHC-type molecules and HLA-type molecules is hereby, withdrawn.

In light of Applicant's amendments filed 08/04/08, the 112 2nd rejection of the claims based on "folding peptide" is hereby, withdrawn.

In light of Applicant's amendments and remarks filed 08/04/08 on pages 1-3, the 112 first rejection of enablement is hereby, withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 22, 23, 25, 34-37, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hildebrand et al. (US 2003/0166057) in view of Whitehead et al (US 4,554,088)

Hildebrand et al disclose recombinant class II HLA molecules (e.g., abstract, paragraphs 0120-0122, para. 0200, para.0212). Hildebrand et al disclose that these molecules can be used in methods for the removal of anti-HLA antibodies (para.0120).

Hildebrand et al differ from the instant invention in failing to teach the step of contacting the sample and removing the bound anti-HLA antibodies.

Whitehead et al disclose methods for depleting a sample of a biological molecule of interest by contacting the sample with an immobilized bioaffinity adsorbent (abstract col 2, col 6-8, 10 and 17). Whitehead et al disclose that the bioaffinity adsorbent can be any biological or other molecule capable of specific or nonspecific binding or interaction with another biological molecule (col 7). Whitehead et al disclose that the analyte can be immobilized to a magnetic particle. (col 6). Whitehead et al disclose removing the bound biological molecule from the sample to deplete the sample.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize the recombinant HLA molecules as taught by Hildebrand et al on magnetic particles such as taught by Whitehead et al and incorporate contacting and removing steps as taught by Whitehead et al because Hildebrand et al specifically teaches that these molecules can be used in methods of removing anti-HLA antibodies and Whitehead et al specifically teaches steps of removing a biological molecule from a sample and also teaches that the bioaffinity adsorbent can be any biological or other molecule capable of specific or nonspecific binding or interaction with another biological molecule.

6. Claims 22, 23, 25, 34-37, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitehead et al (US 4,554,088) in view of Viken et al (Human Immunology, Vol 44, 1995, pp. 63-69).

Whitehead et al disclose methods for depleting a sample of a biological molecule of interest by contacting the sample with an immobilized bioaffinity adsorbent (abstract

col 2, col 6-8, 10 and 17). Whitehead et al disclose that the bioaffinity adsorbent can be any biological or other molecule capable of specific or nonspecific binding or interaction with another biological molecule such as antibody/antigen (col 7). Whitehead et al disclose that the analyte can be immobilized to a magnetic particle. (col 6). Whitehead et al disclose removing the bound biological molecule from the sample to deplete the sample.

Whitehead et al differs from the instant invention in failing to specifically teach the bioaffinity adsorbent is a recombinant MHC Class II or HLA Class II molecule and fails to teach the antibody is an HLA antibody.

Viken et al disclose bioaffinity adsorbents which interact with each other (pgs 63-64). Viken et al disclose that the bioaffinity adsorbents can be recombinant HLA Class II molecules which bind specifically to antibodies of a sample (anti-HLA antibodies).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate recombinant HLA molecules such as taught by Viken et al as the antigen into the method of Whitehead et al because Whitehead et al is generic with respect to the biological molecule to be depleted and one would use the appropriate bioaffinity reagent, i.e. recombinant HLA molecule to deplete the desired biomolecule of interest, in this case MHC molecule antibodies. Thus, one of ordinary skill in the art would have a reasonable expectation of success incorporating recombinant molecules such as taught by Viken et al into the method of Whitehead et al.

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hildebrand et al in view of Whitehead et al as applied to claims 22, 23, 25, 34-37, 46 and 47 above, and further in view of Lee et al (US 6,150,122).

See above for the teachings of Hildebrand et al and Whitehead et al.

Hildebrand et al and Whitehead et al differ from the instant invention in failing to teach the sample is a serum sample.

Lee et al discloses that it is known in the art that serum samples from patients comprise Anit-HLA antibodies (e.g., abstract , col 2, 3, col 6). Lee et al disclose immobilized class II antigens for binding to the antibodies of the sample.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a serum sample as taught by Lee et al because Hildebrand et al and Whitehead et al are generic with respect to the sample and because Lee et al shows that it is known in the art that serum samples comprise anti-HLA antibodies and one would use the appropriate sample to remove the desired antibodies, in this case anti-HLA antibodies. Therefore, one of ordinary skill in the art would have a reasonable expectation of success incorporating a serum sample such as taught by Lee et al into the modified method of Hildebrand et al.

Response to Arguments

8. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Mark L. Shibuya, Ph.D./
Supervisory Patent Examiner, Art Unit 1641